GOVERNMENT OF INDIA
HEALTH AND FAMILY WELFARE
LOK SABHA

UNSTARRED QUESTION NO:6368
ANSWERED ON:07.05.2003
REGISTRATION OF FOREIGN SUPPLIERS
HARIBHAU MAHALE

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the Government policy for Registration of foreign suppliers of Drugs by the Drugs Controller of India (DCI);

(b) whether the Government are also insisting on registration for intermediates and chemicals which go to into manufacturing of bulk drugs in the country; and

(c) if so, the justification of this policy?

Answer

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA)

(a): Government of India, Ministry of Health and Family Welfare have published a Gazette Notification GSR No.604(E) dated 24.8.2001 amending the various provisions of the Drugs and Cosmetics Rules, thereby introducing a new provision for the registration of the manufacturing premises of foreign drug manufacturers and the individual drugs prior to their import into the country. The notification has also introduced few other provisions viz. enhanced import licence fees, increased validity period of licence, deletion of exemption from requirement of import licence for bulk drugs for actual users, requirement of minimum 60% of retained shelf life for imported drugs and provisions for import of small quantities of new drugs by Govt. hospitals for treatment of their own patients etc.

(b)&(c): No, Sir. Under Rule 24-A(8), no Registration Certificate is required in respect of an inactive bulk substance to be used for a drug formulation, with or without pharmacopoeial conformity. However, certain drugs like Pencillin G, Erythromycin, Tetracycline, Oxytetracycline, Estradion, Dexamethasone, Prednisolone etc., which are used as drugs as well as also used as a raw material for the manufacture of other drugs and their salts may required registration under the said Notification.